AUG 21 2000

K001462

V. 510(K) SUMMARY: CARESIDE™ *HEMOGLOBIN* SAFETY AND EFFECTIVENESS

I. Applicant Information

A.	Applicant Name	**CARESIDE, Inc.**
B.	Applicant/Manufacturer Address	6100 Bristol Parkway Culver City, CA 90230
C.	Telephone Number	310-338-6767
D.	Contact Person	Kenneth B. Asarch, Pharm.D., Ph.D.
E.	FAX Number	310-338-6789
F.	e-Mail Address	AsarchK@CARESIDE.com
G.	Date 510(k) Summary prepared	May 9, 2000

II. Device Information

A.	Device Name (Trade)	**CARESIDE™ *Hemoglobin***
B.	Device Name (Classification)	**Hemoglobin** test system
C.	Device Classification	Hematology and pathology panel **Hemoglobin** test system Regulation Number: 21 CFR 864.7500 Regulatory Class: 2 Classification Number: 2
D.	Special controls and performance standards	None applicable

III. Substantial Equivalence Claim

A. <u>General equivalency claim</u>

The ability to measure analytes in dry film and other formats is widely recognized and has gained widespread acceptance for use in hemoglobin and chemistry tests.

Hemoglobin *in vitro* diagnostic products, in both dry film and other formats, are already on the U.S. market.

B. <u>Specific equivalency claim</u>

This CARESIDE™ *Hemoglobin* test is substantially equivalent in intended use and performance to the Kodak Ektachem DT slides for the quantitative measurement of hemoglobin on the DT 60 II system (currently marketed by Johnson and Johnson, Inc.). Both are based on the principle of dry film and are read by reflectance photometry; however, the Kodak Ektachem DT Slide method is based upon the conversion of hemoglobin to methemoglobin and subsequently to isothiocyanmethemoglobin while the CARESIDE method is based upon the measurement of oxyhemoglobin.

Name of Predicate Device:	Kodak Ektachem DT Slides (currently marketed by Johnson and Johnson) for the **DT 60 II system**.
Predicate Device 510K number:	**K912844/A**
Product Code:	81KHG

IV. Device Description

CARESIDE™ *Hemoglobin* cartridges are used with the CARESIDE *Analyzer*™ to measure hemoglobin in whole blood specimens. The CARESIDE™ *Hemoglobin* cartridge, a single use disposable *in vitro* diagnostic test cartridge, delivers a measured volume of whole blood to a dry film to initiate the measurement of hemoglobin. The film cartridge (patent pending) contains everything necessary to measure hemoglobin.

A. Explanation of Device Function

Each CARESIDE™ *Hemoglobin* cartridge consists of a hemoglobin-specific multi-layer film mounted in a plastic base with a hinged lid. The user introduces the specimen into the cartridge Sample Well, closes the lid and inserts the cartridge into the CARESIDE *Analyzer*™.

Once loaded, the CARESIDE *Analyzer*™ scans the cartridge barcode and spins the cartridge to move the sample from the Sample Well into the cartridge channels and chambers. Sample (8.5 microliters) remains in the metering passage. Any excess sample flows into an overflow well.

The sample is automatically dispensed onto the multi-layer film. The spreading layer distributes the specimen uniformly. The color intensity of the oxyhemoglobin, as measured by the amount of reflected light at 570 nanometers, directly relates to the hemoglobin concentration of the specimen.

Test Reaction Sequence:

Hemoglobin + O_2 ⟶ Oxyhemoglobin

As the cartridges spin, a photodiode measures reflectance of light emitted by a wavelength-specific light emitting diode (LED) over a fixed time period. The analyzer uses the reflectance measurements and the lot-specific standard curve to calculate hemoglobin concentration.

The CARESIDE *Analyzer* provides a calculated hematocrit result, expressed as a percent. The calculated hematocrit is obtained by multiplying the measured hemoglobin concentration (expressed in g/dL) by 2.94 (J.D. Bower, P.G. Ackerman and G. Toto, eds., "Evaluation of Formed Elements of Blood," in Clinical Laboratory Methods (St. Louis: The C.V. Mosby Company,. 1974). The calculation assumes a normal mean corpuscular hemoglobin concentration.

B. Test Summary

Hemoglobin is a protein in red blood cells that serves as the oxygen carrier in human blood. Hemoglobin levels in blood can be estimated from the hematocrit, however direct measurement is preferred. Anemia is defined by low hemoglobin levels. High hemoglobin levels may indicate an increased concentration of red blood cells, termed polycythemia.

V. Intended Use

A. Intended Use

The CARESIDE™ *Hemoglobin* cartridge is intended for *in vitro* diagnostic use in conjunction with the CARESIDE *Analyzer*™ to quantitatively measure hemoglobin in whole blood.

B. Indications for Use

This product is indicated for use in the diagnosis and treatment of patients with anemia and polycythemia.

VI. Technological Characteristics

A. Similarities

	CARESIDE™ *Hemoglobin*	**Ektachem Kodak DT HB Slides**
Intended Use	Primarily to aid in the diagnosis and treatment of patients with anemia and polycythemia.	Same
Indications	For *in vitro* diagnostic use	For *in vitro* diagnostic use
Measurement	Quantitative	Same
Method Principle	Dry film	Dry film
Specimen dilution	Not required	Same
Materials	None	$K_3Fe(CN)_6$
Detector	Reflectance (570 nm)	Reflectance (555 nm)
Test time	Approx. 2 minute for total test cycle.	15 minutes slide warm-up (off-line) plus 5 minutes test time.
Reference Method	Cyanmethemoglobin	Cyanmethemoglobin
Sample Type	EDTA or heparinized whole blood	EDTA, heparinized, or citrate whole blood
Specimen volume	8.5 µl test volume (25 to 50 µl applied volume)	10 µl
Calibration	Calibration information bar-coded on each cartridge. Calibration information may change with each lot.	Run DT II calibrators whenever a new slide lot is used or when necessary.
Quality Control	2 levels	Same
Reporting Units	g/dL	Same

B. Differences

	CARESIDE™ *Hemoglobin*	**Ektachem Kodak DT HB Slides**
Specimen Processing	Not required	Required
Accurate pipetting	Not required	Required
Disposable pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE™ *Hemoglobin*	**Ektachem Kodak DT HB Slides**
Detection limit	4 g/dL	5 g/dL
Reportable range	4 to 20 g/dL	5 to 20 g/dL
Accuracy	Mean recovery 97%	Not provided
Precision	Total CV, 14.7 g/dL, 5.2%	Total CV, 10 g/dL, 2%
Method comparison	CARESIDE™ = 0.98 (Hematil H-2000) + 0.29 g/dL, r = 0.96	
Linearity	Linearity yielded slope and correlation coefficient within acceptable limits.	Not provided
Interference	No significant interference observed at tested concentration of interferent: Ascorbic Acid,.....20 mg/dL Bilirubin .....20 mg/dL Protein .....10 g/dL Triglycerides .....2000 mg/dL	No reported interference

D. Conclusion

The data provided demonstrate that the CARESIDE™ *Hemoglobin* product is as safe, effective, and performs as well as or better than the legally marketed predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 21 2000

Kenneth B. Asarch, Ph.D.
Vice President Quality Systems and
Regulatory Affairs
Careside Hemotology, Inc.
6100 Bristol Parkway
Culver City, California 90230

Re: K001462
Trade Name: CARESIDE™ Hemoglobin
Regulatory Class: II
Product Code: KHG
Dated: July 24, 2000
Received: July 26, 2000

Dear Dr. Asarch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VII. INDICATIONS FOR USE

510(k) Number:

Device Name: CARESIDE™ *Hemoglobin*

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer*™ to measure hemoglobin from whole blood specimens to aid in the diagnosis and treatment of patients with anemia and polycythemia.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Julie E. Makuni

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001462

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)